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EXAMINER

EISENSCHENK, F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1816 | 12 |

1816

DATE MAILED: 12/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 3-22 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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1. Claims 1 and 3-22 are currently pending. Claim 2 has been cancelled.
2. The specification is objected and claims 1, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The claims are directed to a composition comprising a non-fibrotic growth factor [e.g. TGF- β_1] together with an anti-fibrotic agent [e.g. an antibody to TGF- β_1]. The specification fails to provide any direction for the use of such a composition e.g. the specification fails to provide the concentration of agents. Equimolar amounts of such agents will expectedly bind each other and thereby be rendered useless in such a composition for use in treating wounds. *This rejection has not been addressed.*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ammann et al. Ammann teaches compositions comprising TGF- β_3 . Applicants' current claims read on compositions comprising TGF- β_3 with no other fibrotic growth factors present. In view of the recitation of claim 1 of compositions of TGF- β_3 alone, the teachings of Ammann are considered to read on all claims.
5. Claims 1, 2, 6, 12 and 14-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cerletti et al. [EP 0 433 225 (1990)]. Cerletti et al. teach a method for treating wounds using a TGF- β like protein. See page 5, lines 9-19. Cerletti et al. teach TGF- β like proteins refers to TGF- β_1 , TGF- β_2 and TGF- β_3 . See page 4, lines 54-56. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Cerletti et al. is the same as that claimed. Thus, the Cerletti et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

Applicant traverses on the grounds that Cerletti does not teach the non-fibrotic character of TGF- β_3 . However, Cerletti et al. teach a composition comprising TGF- β_3 for use in wound healing. Therefore the Cerletti et al. composition of TGF- β_3 inherently has the same properties as the instant claimed invention. Applicant is again referred to Best. Intended use limitations are not given weight with respect to composition/compound claims. See MPEP 2111.02. The claims

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recite compositions comprising TGF- β_3 alone. A reference teaching TGF- β_3 alone reads on the claimed invention.

6. Claims 1 and 3 are rejected under 35 U.S.C. § 103 as being obvious over Cerletti or Ammann in view of Baird et al. (U.S. Pat. 5,155,214). The teachings of Cerletti and Ammann have been discussed above. The references do not teach combinations of TGF- β_3 and FGF. Baird teaches compositions comprising FGF and the usefulness of such compositions in wound healing. Cerletti and Amman indicate that TGF- β_3 is also useful in the treatment of wound healing. One of ordinary skill in the art would have been motivated to combine two compositions recognized to be useful for the same purpose in order to prepare a third composition useful for the same purposes.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been motivated to combine two compositions recognized to be useful for the same purpose in order to prepare a third composition useful for the same purposes. In view of the references, one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention is prima facie obvious to one of ordinary skill in the art, especially in the absence of evidence to the contrary.

7. No claim allowed.
8. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 308-4242
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. The examiner can normally be reached Monday through Thursday from 6:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.



December 4, 1997

Christopher Eisenschenk, Ph.D.

Primary Examiner

Group 1800